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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,210	03/17/2005	Stephen R. Smith	3323	9149

21834 7590 02/13/2007

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EXAMINER	
DAVIS, RUTH A	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/528,210	SMITH ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on November 24, 2007 have been received and entered into the case. Claims 23 – 48 are canceled; claims 49 – 69 are added. Claims 49 – 69 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, first paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 49 – 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unilever PLC in view of Medipharm, Ibrahim, and Nippon.

Applicant claims an antimicrobial composition used as an agent to suppress the growth of enteric pathogens such as Clostridium perfringens, Esherichia coli, Salmonella typhimurium and Salmonella mbandaka, either in powdered or aqueous solution or water-soluble form comprising a cell wall lysing substance or salt such as lysozyme, dried egg powder or albumen and a sequestering agent such as an organic acid or a metal chelator which is administered to feedstock as a feed additive to prevent and treat gastrointestinal infections such as necrotic enteritis and diarrheal disease in livestock. Applicant claims the composition ratio of such composition being 2:5:3 by weight. Further applicant claims the use of dried egg powder in such composition is capable of suppressing microbes such as molds and viruses and also enzymes like proteases and lipases in livestock gut. Further, applicant claims cell wall lysing substance or salt, dried egg powder or albumen, a sequestering agent and a lantibiotic such as nisin, whose ratio in composition is 50:150:50:20.

Unilever PLC disclose a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of Listeria monocytogenes and also other microorganisms such as lactic acid bacteria which is used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics

and pharmaceutical products (see abstract). They disclose the effectiveness of using lysozyme in combination with citric acid or EDTA and other chelators or an antimycotic such as PimaricineTM in foods to inhibit Listeria monocytogenes, bacteria and yeasts (see pg. 2 "Use of lysozyme" section). Unilever discloses a strong synergism existing between the action of lysozyme, nisin and citric acid (EDTA or salts thereof can be substituted for citric acid). These three ingredients used together effectively prevent the growth of many strains of bacteria and are much more effective when used in combination than when used alone (see pg. 3 "Brief summary of invention and detailed description" paragraphs). They also suggest that antimycotics such a PimaricineTM , which suppress the growth of molds and yeasts, can be used in combination with such mixture and further suggest that at least one antibacterial compound must be present in the synergistic composition (pg. 4 lines 20-24). Thus Unilever's invention is a composition, which has improved antibacterial properties, comprising a mixture of at least one representative of each group (a) a cell wall lysing substance (b) an antibacterial compound and (c) and adjuvant such as an organic acid or sequestering agent and further claims the following ratio of such composition (a) 5-2000 mg : (b) 5 x 10^3 -5 x 10^6 IU : (c) 0.5-100 g.

Unilever differs from the claims in that their composition is not disclosed as containing egg powder or albumen and further to suppress the growth of enteric pathogens, specifically Clostridium sp. , E.cofi and Salmonella sp. However, Medipharm discloses an oral product for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of Clostridium sp., E.cofi and Salmonella sp. The oral compositions raw material is liquid eggs, which are freeze-dried resulting in a powder form product, from which antibodies are obtained.

The product exists in a paste, water-soluble powder formula which may be mixed with water, and a powder formula (see pg. 3 "Principle of invention" section). Further support of the why one would use egg or albumin in an antimicrobial composition is provided by Ibrahim. Ibrahim discloses that an avian egg is one of many natural antimicrobial systems available. Egg whites, also known as albumin, is the eggs second line of defense against bacteria after the shell and membranes. The proteins in egg whites are thought to prevent invasion of microorganisms into the yolk and most posses antimicrobial properties which hinder the growth and spread of microorganisms. Such antimicrobial properties include lysozyme, which hydrolyzes the peptidoglycan of bacterial cell walls, ovotransferrin, which chelates metal ions, vitamin binding proteins and proteinase inhibitors (see introduction). Even further support is Nippon disclosing an antiviral agent containing albumen as an active component for the suppression of viruses such as rotavirus (see abstract).

One of ordinary skill in the art would therefore have been motivated by Ibrahim's disclosure of the antimicrobial properties eggs possess and to apply this knowledge to the composition in Medipharms application used for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of Clostridium sp., E.cofi and Salmonella sp. and to further apply these advantages to the composition disclosed by Unilever containing a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agentcitric acid or another food-grade adjuvant, effectively preventing the growth of Listeria monocytogenes and also other microorganisms such as lactic acid bacteria which is used

in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products.

With respect to the composition ratios in claims 10,16 and 22, optimizing the ratio as disclosed by Unilever is practiced through routine scientific experimentation. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. See MPEP 2144.05

Thus the claimed invention as a whole is prima facie obvious over the prior art.

Response to Arguments

Applicant argues that the references do not teach an oral composition that is administered to livestock and that the references are non-analogous to each other.

However, these arguments fail to persuade because Unilever clearly teaches the compositions may be used in feedstuffs (or orally ingestible compositions) (p.3). Furthermore, the supporting references teach oral antibiotic compositions as well. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited referenced to combine the instant ingredients with a reasonable expectation for successfully obtaining an effective, orally administrable antibiotic composition.

In response to applicant's argument that the references are not analogous to each other, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was

concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, each of the cited references teach components of the claimed invention which may be orally administered to animal livestock, and have antibiotic effects.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TMG

February 7, 2007

RUTH A. DAVIS
PATENT EXAMINER